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Stadol® NN
(butorphanol tartrate)

the effective analgesic with the safety difference

Brief Summary of Prescribing Information
STADOL® (butorphanol tartrate)
For complete information, consult Official Package Circular.
(2) 12/10/79

INDICATIONS AND USAGE—Stadol is recommended for the relief of moderate to severe pain. Stadol can also be used for preoperative or preanesthetic medication, as a supplement to balanced anesthesia, and for the relief of prepartum pain.

CONTRAINDICATIONS—Stadol should not be administered to patients who have been shown to be hypersensitive to it.

WARNINGS—Patients Physically Dependent on Narcotics: Because of its antagonist properties, Stadol is not recommended for patients physically dependent on narcotics. Detoxification in such patients is required prior to use.
Due to the difficulty in assessing addiction in patients who have recently received substantial amounts of narcotic medication, caution should be used in the administration of Stadol. Detoxification of such patients prior to usage should be carefully considered.

Drug Dependence: Special care should be exercised in administering Stadol to emotionally unstable patients and to those with a history of drug misuse. When long-term therapy is contemplated, such patients should be closely supervised. Even though Stadol has a low physical dependence liability, care should be taken that individuals who may be prone to drug abuse are closely supervised. It is important to avoid increases in dose and frequency of injections by the patient and to prevent the use of the drug in anticipation of pain rather than for the relief of pain.

Head Injury and Increased Intracranial Pressure: Although there is no clinical experience in patients with head injury, it can be assumed that Stadol, like other potent analgesics, elevates cerebrospinal fluid pressure. Therefore the use of Stadol in cases of head injury can produce effects (e.g., miosis) which may obscure the clinical course of patients with head injuries. In such patients Stadol must be used with extreme caution and only if its use is deemed essential.

Cardiovascular Effects: Because Stadol increases the work of the heart, especially the pulmonary circuit, the use of this drug in acute myocardial infarction or in cardiac patients with ventricular dysfunction or coronary insufficiency should be limited to those who are hypersensitive to morphine sulfate or meperidine.

PRECAUTIONS—Certain Respiratory Conditions: Because Stadol causes some respiratory depression, it should be administered only with caution and low dosage to patients with respiratory depression (e.g., from other medication, uremia, or severe infection), severely limited respiratory reserve, bronchial asthma, obstructive respiratory conditions, or cyanosis.

Impaired Renal or Hepatic Function: Although laboratory tests have not indicated that Stadol causes or increases renal or hepatic impairment, the drug should be administered with caution to patients with such impairment. Extensive liver disease may predispose to greater side effects and greater activity from the usual clinical dose, possibly the result of decreased metabolism of the drug by the liver.

Biliary Surgery: Clinical studies have not been done to establish the safety of Stadol administration to patients about to undergo surgery of the biliary tract.

Usage as a Preoperative or Preanesthetic Medication: Slight increases in systolic blood pressure may occur, therefore caution should be employed when Stadol is used in the hypertensive patient.

Usage in Balanced Anesthesia: The use of pancuronium in combination with Stadol may cause an increase in conjunctival changes.

Usage in Pregnancy: The safety of Stadol for use in pregnancy prior to the labor period has not been established; therefore, this drug should be used in pregnant patients only when in the judgment of the physician its use is deemed essential to the welfare of the patient.
Reproduction studies have been performed in rats, mice and rabbits and have revealed no evidence of impaired fertility or harm to the fetus due to Stadol at about 2.5 to 5 times the human dose.

Usage in Labor and Delivery: Safety to the mother and fetus following administration of Stadol during labor has been established. Patients receiving Stadol during labor have experienced no adverse effects other than those observed with commonly used analgesics. Stadol should be used with caution in women delivering premature infants.

Usage in Nursing Mothers: The use of Stadol in lactating mothers who are nursing their infants is not recommended since it is not known whether this drug is excreted in human milk. Stadol has been used safely for labor pain in mothers who subsequently nursed their infants.

Usage in Children: Safety and efficacy in children below age 18 years have not been established.

ADVERSE REACTIONS—The most frequent adverse reactions in 1250 patients treated with Stadol are: sedation (503, 40%), nausea (82, 6%), clammy/sweating (76, 6%).
Less frequent reactions are: headache (35, 3%), vertigo (33, 3%), floating feeling (33, 3%), dizziness (23, 2%), lethargy (19, 2%), confusion (15, 1%), lightheadedness (12, 1%).
Other adverse reactions which may occur (reported incidence of less than 1%) are:
CNS: nervousness, unusual dreams, agitation, euphoria, hallucinations
Autonomic: flushing and warmth, dry mouth, sensitivity to cold
Cardiovascular: palpitation, increase or decrease of blood pressure
Gastrointestinal: vomiting
Respiratory: slowing of respiration, shallow breathing
Dermatological: rash or hives
Eye: diplopia or blurred vision

OVERDOSAGE—Manifestations: Although there have been no experiences of overdosage with Stadol during clinical trials, this may occur due to accidental or intentional misuse as well as therapeutic use. Based on the pharmacology of Stadol, overdosage could produce some degree of respiratory depression and variable cardiovascular and central nervous system effects.

Treatment: The immediate treatment of suspected Stadol overdosage is intravenous naloxone. The respiratory and cardiac status of the patient should be evaluated constantly and appropriate supportive measures instituted, such as oxygen, intravenous fluids, vasopressors and assisted or controlled respiration.

HOW SUPPLIED—Stadol (butorphanol tartrate) Injection for I.M. or I.V. use, is available as follows:
NDC 0015-5644-20—2 mg per ml, 2-ml vial
NDC 0015-5645-20—1 mg per ml, 1-ml vial
NDC 0015-5646-20—2 mg per ml, 1-ml vial
NDC 0015-5646-23—2 mg per ml, 1-ml Disposable Syringe
NDC 0015-5648-20—2 mg per ml, 10-ml multi-dose vial

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Dilaudid® (C II)
hydromorphone HCl
Warning: May be habit forming

INDICATIONS AND USAGE: DILAUDID is indicated for the relief of moderate to severe pain such as that due to:
Surgery/Cancer/Trauma (soft tissue & bone)/Biliary Colic/Myocardial Infarction/Burns/Renal Colic
CONTRAINDICATIONS: As is morphine, DILAUDID is contraindicated in patients known to have a hypersensitivity to it; in the presence of an intracranial lesion associated with increased intracranial pressure; and whenever ventilatory function is depressed (chronic obstructive pulmonary disease, cor pulmonale, emphysema, kyphoscoliosis, status asthmaticus).
WARNINGS
Respiratory Depression: DILAUDID produces dose-related respiratory depression by acting directly on brain stem respiratory centers. DILAUDID also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing.
Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce effects which may obscure the clinical course of patients with head injuries.
Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.
PRECAUTIONS
Special Risk Patients: DILAUDID should be used with caution in elderly or debilitated patients and those with impaired renal or hepatic function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. As with any narcotic analgesic agent, the usual precautions should be observed and the possibility of respiratory depression should be kept in mind.
Cough Reflex: DILAUDID suppresses the cough reflex; as with all narcotics, caution should be exercised when DILAUDID is used postoperatively and in patients with pulmonary disease.
Usage in Ambulatory Patients: Narcotics may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.
Drug Interactions: Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, tranquilizers, sedative-hypnotics, tricyclic antidepressants or other CNS depressants (including alcohol) concomitantly with DILAUDID may exhibit an additive CNS depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.
Parenteral Administration: The parenteral form of DILAUDID may be given intravenously, but the injection should be given very slowly. Rapid intravenous injection of narcotic analgesics increases the possibility of side effects such as hypotension and respiratory depression.
Pregnancy: Pregnancy Category C. DILAUDID has been shown to be teratogenic in hamsters when given in doses 600 times the human dose. There are no adequate and well-controlled studies in pregnant women. DILAUDID should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose. There is no consensus on the best method of managing withdrawal. Chlorpromazine 0.7 to 1.0 mg/kg q6h, phenobarbital 2 mg/kg q6h, and paregoric 2 to 4 drops/kg q4h, have been used to treat withdrawal symptoms in infants. The duration of therapy is 4 to 28 days, with the dosages decreased as tolerated.
Labor and Delivery: As with all narcotics, administration of DILAUDID to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.
Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from DILAUDID, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric Use: Safety and effectiveness in children have not been established.
FD&C Yellow No. 5: DILAUDID 1 mg, 2 mg and 4 mg color-coded tablets contain FD&C Yellow No. 5 (tartrazine) dye which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) dye sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.
ADVERSE REACTIONS
Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.
Gastrointestinal System: Nausea and vomiting occur infrequently; they are more frequent in ambulatory than in recumbent patients. The antiemetic phenothiazines are useful in suppressing these effects; however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of DILAUDID may produce constipation.
Cardiovascular System: Circulatory depression, peripheral circulatory collapse and cardiac arrest have occurred after rapid intravenous injection. Orthostatic hypotension and fainting may occur if a patient stands up suddenly after receiving an injection of DILAUDID.
Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.
Respiratory Depression: DILAUDID produces dose-related respiratory depression by acting directly on brain stem respiratory centers. DILAUDID also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride, 0.005 mg/kg intravenously. Apply other supportive measures when indicated.
DRUG ABUSE AND DEPENDENCE: DILAUDID is a Schedule II narcotic. Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, DILAUDID should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when DILAUDID is used for a short time for the treatment of pain. Physical dependence, the condition in which continued administration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued narcotic use, although some mild degree of physical dependence may develop after a few days of narcotic therapy. Tolerance, in which increasingly large doses are required in order to produce the same degree of analgesia, is manifested initially by a shortened duration of analgesic effect, and subsequently by decreases in the intensity of analgesia. The rate of development of tolerance varies among patients. 2/81 6573

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